

# RULE 63 (37 CFR 1.63) DECLARATION FOR PATENT APPLICATION IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe that, I am an original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled "USE OF NEUROTOXIN THERAPY FOR TREATMENT OF UROLOGICAL-NEUROLOGICAL DISORDERS ASSSOCATED WITH PROSTATE CANCER", the specification of which has been prepared and filed on September 4, 2003, receiving Serial No. 10/655,889, and further identified as Attorney File No. 2848-28-PUS-1-1.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability in accordance with 37 CFR 1.56(a) and (b) as set forth on the attached sheet indicated Page 3 hereof and which I have read.

I hereby claim priority benefits under 35 U.S.C. 119(e) of any provisional application(s) for patent listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior applications in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information material to patentability in accordance with 37 CFR 1.56(a) and (b) which occurred between the filing date(s) of the prior application(s) and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	<u>Status</u>
60/052,580	July 15, 1997	abandoned

I hereby claim the benefit under 35 U.S.C. 120/365 of all United States and PCT international applications listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior applications in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information material to patentability in accordance with 37 CFR 1.56(a) and (b) which occurred between the filing date(s) of the prior application(s) and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status: patented, pending, abandoned
09/978,982	October 15, 2001	patented
09/463,040	January 17, 2000	patented
PCT/US98/14625	July 15, 1998	expired

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1) Inventor's Signature Sund Nall Date 19 May 2004

Inventor's Name:

David Allen, on behalf and as agent of Richard A. Schmidt

Citizenship:

U.S.

Residence:

1042 Eldorado Drive

Superior, Colorado 80027

Post Office Address:

Same as Residence

# 37 CFR §1.56(a) and (b) DUTY TO DISCLOSE INFORMATION MATERIAL TO PATENTABILITY

- A patent by its very nature is affected with a public interest. The public interest is best served, (a) and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:
- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
  - (2) It refutes, or is inconsistent with, a position the applicant takes in:
    - (i) Opposing an argument of unpatentability relied on by the Office, or
    - (ii) Asserting an argument of a patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.\*

\*Note, 37 CFR §1.97(h) states: "The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56(b)."

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MAY 2 0 2004 (2) IN THE UNITED STATES PAT	ENT AND TRADEMARK OFFICE
In Re the Application of:	) )
SCHMIDT	) .
Serial No.: 10/655,889	)
Filed: September 4, 2003	) STATEMENT BY ASSIGNEE ) Under 37 CFR 3.73(b) and
Atty. File No.: 2848-28-PUS-1-1	) 37 CFR 1.47(b)
For: "USE OF NEUROTOXIN THERAPY FOR TREATMENT OF UROLOGICAL-NEUROLOGICAL DISORDERS ASSSOCIATED WITH PROSTATE CANCER"	) ) EXPRESS MAIL: EV368036430US )

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

### Dear Sir:

I, David Allen, an officer authorized to act on behalf of The Regents of the University of Colorado, which is the assignee of the entire right, title and interest in the above-identified application, hereby state that the filing date of the above-identified application was necessary to preserve the rights of the parties in the above-identified application and to prevent irreparable damage to the parties.

This application claims priority under 35 U.S.C. § 120 as a continuation-in-part from U.S. Patent Application Serial No. 09/978,982, which issued as U.S. Patent No. 6,667,041 on December 23, 2003, which claims priority under 35 U.S.C. § 120 as a continuation of U.S. Patent Application Serial No. 09/463,040, filed January 17, 2000, which issued as U.S. Patent No. 6,365,164. Denial of the filing date for the present application (U.S. Patent Application Serial No. 10/655,889) would result in a loss of rights to the September 4, 2003 filing date for the claims of this continuation-in-part application.

The Regents of the University of Colorado, is the assignee of the entire right, title and interest in the patent application identified, which claims the benefit of priority under 35 U.S.C. § 120 to U.S. Patent Application Serial No. 09/978,982 and U.S. Patent Application Serial No. 09/463,040. The assignment is by virtue of: (1) an assignment from the inventor of U.S. Patent Application Serial No. 09/463,040 and all continuation, divisional, continuation-in-part and reissue applications thereof to University Technology Corporation, recorded in the U.S. Patent Office on September 25, 2000, at Reel 010137, Frame 0410; and (2) an assignment from University Technology Corporation of U.S. Patent Application Serial No. 09/978,982 and U.S. Patent Application Serial No. 09/463,040, and any continuations, divisions, continuations-in-part, reissues and extensions thereof, to The Regents of the University of Colorado, recorded in the Patent and Trademark Office on February 3, 2003, at Reel 010137, Frame 0410. Copies of the above-identified Assignments are attached hereto.

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United Sates Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 19 MM 2004

David Allen

Associate Vice President of Technology Transfer The Regents of the University of Colorado

#### ASSIGNMENT

WHEREAS, I, Richard A. Schmidt of 12136 W. 75th Lane, Arvada, Colorado 80005, have invented a certain new and useful invention entitled "USE OF NEUROTOXIN THERAPY FOR TREATMENT OF UROLOGIC AND RELATED DISORDERS", for which an application for Letters Patent of the United States has been prepared and filed on January 17, 2000, receiving Serial No. 09/463,040, and further identified as Attorney File No. 2848-28-PUS;

NOW THEREFORE, be it known that I, the said inventor, for and in consideration of certain good and valuable consideration, the sufficiency and receipt of which is hereby acknowledged, at the request of the assignee do sell, assign and transfer unto said assignee, University Technology Corporation, a non-profit organization corporation having a place of business at 3101 Iris Avenue, Suite 250, Boulder, Colorado 80301, its successors, legal representatives and assigns, the aforesaid application for the territory of the United States of America and all continuation, divisional, continuation-in-part and reissue applications, all patent applications in foreign countries, all applications pursuant to the Patent Cooperation Treaty, and all applications for extension filed or to be filed for the invention, and all Letters Patent, Invention Registrations, Utility Models, Extensions or Reissues and other patent rights, obtained for the invention in the United States or any other country; I also assign any right, title or interest in and to the invention which has not already been transferred to the assignee; I warrant that I have made no assignment of the invention, application or patent therefor to a party other than University Technology Corporation and I am under no obligation to make any assignment of the invention, application, or patent therefor to any other party; and I further agree to cooperate with the assignee hereunder in the obtaining and sustaining of any and all such Letters Patent and in confirming assignee's exclusive ownership of the invention, but at the expense of said assignee.

The Commissioner of Patents is hereby authorized and requested to issue the Letters Patent · solely in accordance with the terms of this Assignment, to University Technology Corporation, its successors, legal representatives and assigns, as the assignee of the entire right, title and interest therein.

IN WITNESS WHEREOF, the parties hereto have executed this Assignment as of the date indicated hereunder.

By: Richard D. Schmiett
Richard A. Schmidt

STATE OF Corado )
COUNTY OF Officion ) ss

Before me, a Notary Public in and for said County and State, personally appeared Richard A. Schmidt, known to me to be the person whose name is subscribed to the foregoing instrument, and acknowledged to me that he executed the same for the purposes and considerations therein expressed.

Given under my hand and seal of office this day of

Notary Public

My Commission Expires: 1 May 06, 2000

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### PATENT ASSIGNMENT

THIS ASSIGNMENT is made effective as of April 30, 2002, by and between University Technology Corporation, a Colorado nonprofit corporation ("Assignor") and The Regents of the University of Colorado, a body corporate ("Assignee").

WHEREAS, Assignee wishes to acquire and Assignor wishes to assign all of its right, title and interest in, to and under the patents and patent applications listed on Exhibit A attached hereto (collectively, the "Patent Properties").

NOW, THEREFORE, for good and valuable consideration paid by Assignee to Assignor, receipt of which is hereby acknowledged, Assignor agrees to sell, assign, transfer and set over and does hereby sell, assign, transfer and set over to Assignee, its entire right, title and interest in and to the Patent Properties, as well as the inventions claimed in such Patent Properties, for the United States and for all foreign countries, including any continuations, divisions, continuations-in-part, reissues or extensions thereof for its own use and enjoyment, and for the use and enjoyment of its successors, assigns or other legal representatives, as fully and entirely as the same would have been held and enjoyed by Assignor if this assignment and sale had not been made; together with all claims for damages by reason of past, present or future infringement or other unauthorized use, with the right to sue for, and collect the same for its own use and enjoyment, and for the use and enjoyment of its successors, assigns, or other legal representatives.

Assignor shall provide to Assignee, its successors, assigns or other legal representatives, cooperation and assistance at Assignee's reasonable request and reasonable expense (including the execution and delivery of any and all affidavits, declarations, oaths, assignments, powers of attorney or other documentation as may be reasonably required): (1) in the preparation and prosecution of any applications covering inventions assigned herein; (2) in the prosecution or defense of any interference, opposition, reexamination, reissue, infringement or other proceedings that may arise in connection with any of the patent rights assigned herein, including testifying as to any facts relating to the patent rights assigned herein and this Assignment; (3) in obtaining any additional patent protection that Assignee may deem appropriate which may be secured under the laws now or hereafter in effect in the United States or any other country; and (4) in the implementation or perfection of this Assignment.

IN TESTIMONY WHEREOF, the undersigned has executed this Patent Assignment to be effective as of the 30<sup>th</sup> day of April, 2002.

ASSIGNEE:

THE REGENTS OF THE UNIVERSITY OF COLORADO, a body corporate

Its: President

**ASSIGNOR:** 

UNIVERSITY TECHNOLOGY CORPORATION, a Colorado nonprofit

corporation

STATE OF COLORADO COUNTY OF BOULDER	) ) ss. )	·	<del>-</del>
Before me, the understappeared John W. Bliss, as acknowledged the execution 2002.	designee for the Pres		of Colorado, and
IN WITNESS WHERE	OF, I have hereunto subs	cribed my name and affixe	d my seal.
	Notary Par My comm	blic ission expires: 2/8/03	
	•	•	•
STATE OF COLORADO )	•		• •
)	SS.		•
COUNTY OF BOULDER )			
Before me, the undersi appeared Jerry Donahue, Pres- execution of the foregoing Pater	ident of University Tecl		• • •
IN WITNESS WHERE		cribed my name and affixed	d my seal.

Notary Public
My commission expires: Lugust 26, 2003